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EXAMINER

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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID GREWE and DAVID C. MAJERCAK

Appeal 2008-4373
Application 10/691,823
Technology Center 3700

Oral Hearing Held: November 6, 2008

Before TONI R. SCHEINER, ERIC B. GRIMES and FRANCISCO C.
PRATS, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

GEORGE GERSTMAN, ESQUIRE
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The above-entitled matter came on for hearing on Thursday,
November 6, 2008, commencing at 9:02 a.m., at the offices of the U.S.
Patent and Trademark, 600 Dulany Street, Alexandria, Virginia, before
Mario A. Rodriguez, CMRS, CCR No. 0315162, Notary Public.

PROCEEDINGS

MR. GERSTMAN: Good morning.

JUDGE SCHEINER: Good morning, Mr. Gerstman.

Whenever you're ready.

MR. GERSTMAN: I'm ready.

JUDGE SCHEINER: Okay. Good morning.

MR. GERSTMAN: This appeal concerns an application relating to when claims all call for a steerable guide wire.

And a guide wire is -- I brought one with me. I thought it would be helpful to have the different types of items with me.

The guide wire is a thin wire that -- I would be glad to pass it up.

JUDGE SCHEINER: Can we see? Is it all right to touch it?

MR. GERSTMAN: Oh, yes.

It's really a thin wire that's passed through the artery. Typically, it's inserted into the femoral artery in the groin and snaked through an artery in order to allow a catheter to go over it and be placed -- it guides a catheter which is put over it.

So the guide wire is used as the guide. It's put in first. It's inserted first, and thereafter can be used to guide the catheter which is an open catheter and slides over the guide wire.

The guide wire also can be used to break up an obstruction as long as it's a light obstruction.

The idea of the guide wire is because of the way it has to snake through the artery, you want torqueability. So you want it to be able to flex from a long distance. The distal end is the end that's going either to the heart

or to the brain, and the proximal end is the end that's being handled by the physician.

So the physician who is at the proximal end wants to be able to deflect and move the distal end of the guide wire from a long distance, so you need what's called "torqueability" to be able to deflect it properly.

So what this invention concerns is a particular guide wire that has a very unique structure. And, for example, claim -- the claim 1 is directed to the steerable guide wire.

One of the important parts of this guide wire is the -- it has a flexible helical coil at its distal end. And I brought some drawings of that.

This is actually the distal end. Even though it's extremely small, the distal end of the guide wire is shown in the application. There's a flexible helical coil which has these undulations that are, like, sign wave undulations that interlock with each other. This is all in every claim.

JUDGE SCHEINER: These are the drawings from the specification?

MR. GERSTMAN: These are the drawings, right.

This is figure 2 showing the distal end of the guide wire. So you have this helical coil all the way at the end of -- at the distal end of the guide wire. It goes along there (indicating).

And that helical coil is very important and it's very unusual. It has a rectangular cross-sectional configuration. Instead of being circular wire, it's a rectangular wire. And a couple of the claims actually call it a square, although it doesn't have to be exactly square. It could be rectangular.

Then it winds. The way the claims read, "The helical coil has a rectangular cross-section, it has continuous undulations that are lateral to the

length of the tubing." So it winds around lateral and then it extends longitudinally as it winds around laterally.

The undulations of the helical coil interlock with each other and they take the form of a sign wave having positive and negative peaks. And the positive peaks of the sign wave engage the negative peaks.

So the positive peaks of adjacent turns engage the negatives of adjacent turns.

So you have a very unusual helical construction.

JUDGE GRIMES: When you say the positive peaks engage the negative peaks, do you mean that each of the peaks going in a particular direction line up so that the high point of one peak sort of fits into the adjacent peak?

MR. GERSTMAN: Exactly. And they actually engage. They are not spaced. That's a very important point in that it's a difference from a prior art and it also enhances the torqueability of the guide wire.

JUDGE SCHEINER: I'd like to hand this back to you. I'm afraid we might cause a kink or something in it. Thank you.

MR. GERSTMAN: Oh, sure.

Now claim 1 also calls for a deflection member and that deflection member is slidably disposed within the tubing, the flexible tube that comprises this guide wire.

So you have this elongated deflection member that is slidably disposed. The distal portion of this deflection member is flattened and extends in a plane.

You also have a retaining member, a retaining ribbon that's connected

to the deflection member, and the retaining ribbon is also -- it's parallel to it in a parallel plane. You have an attachment member to which the deflection member and the retaining ribbon attach, and the deflection member is such that when it's pulled at the proximal end by the physician, the end of the guide wire goes in one direction and if it's pushed, the end of the guide wire goes in the other direction.

So by pulling and pushing you can move the guide wire a certain way.

By the way, this is a Cordis invent, a subsidiary of Johnson & Johnson, and the Cordis guide wires are extremely important guide wires. They are used even when balloon catheters of other manufacturers are used.

I had four angioplasties on myself, and I would always ask the doctor, What you are using? And they'd always be using Cordis guide wires; they thought they were the best.

Now claim 19 is similar to claim 1, and claim 19 calls for all of the -- everything relating to the helical coil and also mentions that the -- let's see. The distal end is a rounded bead closing the distal end in which is connecting the rest of the -- connecting the helical coil.

Then claim 23 is similar to claim 1, but in claim 23 it also mentions that a part of the deflection member, the proximal portion of the deflection member at the other end is cylindrical.

Now, the examiner applied two references against these claims and to me these references are very, very different and don't show it at all.

The first reference was this Hayzelden, et al. reference. And Hayzelden, et al. relates to ablation catheter. And I brought with me an ablation catheter. It's a completely different thing from a guide wire.

Here's an entire ablation catheter. An ablation catheter has a completely closed tip. It has electrodes at the end, and they actually put an electrical line into it. And the whole idea of an ablation catheter is that you attach it to the heart muscle, and if you have atrial fibrillation, it's used to use RF energy to the heart muscle to change the pathway.

It actually -- I don't know if I should use the term "damages," but it changes the pathways of the heart muscle so that the heart will beat a little differently.

So it's sort of a -- it has to do with curing or trying to cure atrial fibrillation where the cardiologist actually puts it on a high heat, an RF frequency energy at the heart muscle to change it. It has nothing to do with a guide wire whatsoever.

The examiner was saying in the rejection that he was not going to consider the term "steerable guide wire" as meaningful -- in other words -- because it's in the preamble. However, in every claim not only is steerable guide wire in the preamble, but the term is throughout the claim.

These claims are absolutely directed to a steerable guide wire. Not to a catheter, not to an ablation catheter. It meant for steerable guide wires, and that's what so unusual about the whole situation.

Now, in Hayzelden, not only is it an ablation catheter, but it doesn't even have a helical coil.

Hayzelden just discloses a wire braid in it. There's no helical coil. There's no coil with a rectangular cross-sectional configuration. There's no undulations, no interlocking. None of that is present at all.

Not only is Hayzelden only an ablation catheter, but it has nothing relating to the gist of the invent. There's nothing relating to this helical coil at all. Only a wire braid. A completely different thing.

So I think Hayzelden is way outside of what we're talking about.

Now the examiner recognizes that Hayzelden doesn't have all these undulations and sign waves and interlocking and so forth, so the examiner then combined it with Klima, but Klima is also not a wire. It's not a guide wire.

Klima is like this: It's really -- and this is a Cordis catheter. Just an open-ended catheter. In fact, this is what goes over the guide wire. It's completely different from a guide wire and that's what Klima is. Klima is simply a catheter. Not a guide wire at all.

Plus Klima doesn't have any of the -- anything relating to -- let's see. What is it? Anything relating to the deflection member, doesn't have the retaining ribbon. It doesn't have the attachment member. The attachment member is what's at the end of the...

So Klima doesn't have anything relating to a deflection member. Klima doesn't have anything relating to the retaining ribbon. Klima doesn't have anything relating to an attachment member. In fact, in Klima you would never have an attachment member because Klima is an open-ended catheter and the whole idea of the attachment member is it has to be -- that closes up the end of the wire.

JUDGE SCHEINER: The examiner cited Klima for the helical coil; is that correct?

MR. GERSTMAN: Yes.

JUDGE SCHEINER: Okay.

MR. GERSTMAN: It doesn't have those things, plus even the helical coil.

The examiner was saying that the interlocking parts of Klima engage each other, but that's not true. In fact, they are purposely separated. In Klima everything is -- they actually have material that purposely separates. I think figure 14 is the best figure to show that.

14a, in every embodiment of Klima, whenever you have any of the parts of the helical coil, the inter -- nothing interlocks. It's always separated.

JUDGE PRATS: If I may, referring to the portion of Klima that the examiner refers to, column 11, actually maybe a little outside of what the examiner refers to, but column 11 specifically says "the interlocking axial fingers 1077 and 1077 prime help to improve the torsional and actual stiffness of the catheter segment."

So it seems like that you do have "interlocking" and I think interlocking, also one could argue, actually encompasses the engagement talking about your claims. I wonder if you could address that.

MR. GERSTMAN: Okay. In column 11 it says that those fingers are separated by the portion of the -- let's see. Column 11, line 19. In fact, I think I responded to that in my brief. I want to make sure I have the right line.

Oh, yes. It states in column 11 that "the fingers from one support interlock with fingers from the adjacent support on the previous paragraph," let's see line -- that says, "such interlocking occurs while the separation between the adjacent supports is maintained."

I want to find that.

Yes, that part of lines 19 to 21. "The fingers 1077 prime and 1077 are separated by the portion of the flexible outer jacket 90 that fills the serpentine slot 1084."

That's a big difference because in ours we specifically say that they engage each other. So here we're specifically saying they're separated.

JUDGE PRATS: Right. I understand it says it's separated, but immediately following that sentence it talks about how the fingers interlock.

So I'm just trying to resolve the issue we have with the statement that says that the fingers are separated and then we have the following statement that says, Well, they actually interlock. I'm trying to square those statements there.

MR. GERSTMAN: I think when it says "interlock," it means they are sign waved to -- positive to negative and so forth, but it's still separated. I don't think interlock necessarily means they're engaging each other. In ours we say they interlock and they engage.

I think you can interlock. In other words, the negative peaks can interlock with the positive -- or the positive peaks can interlock with the negative valleys or whatever, but they're still separated.

JUDGE PRATS: You're saying, essentially, that the claim should be read that they have to actually touch whereas they don't in Klima?

MR. GERSTMAN: Yes. Every one of the claims actually uses the term "engage." I think that's a very important thing.

This helical construction is really the most important thing, especially when we're talking about a thin guide wire which is -- it's very different from

a catheter. I mean, to get a guide wire to have the proper torqueability is really tricky and that's why Cordis is so unusual. I think that's why people use so many Cordis guide wires because they figured out how to do it.

Our claims are very limited. The claims are very specific and we are sticking with that engaging.

So I think that we have a completely different situation where we have a guide wire that has this great torqueability and it has very specific structure with a very specific type of helical coil.

The catheter has different problems. The coil is -- it's a different coil. It's not any kind of engagement. The catheter does not have any of the other structure and this catheter is an open-ended device that is a completely different structure from a guide wire.

It's very clear in the claims that the claims really are directed to a guide wire and nothing else, and an ablation catheter is also a completely different animal and this ablation catheter has nothing resembling a helical coil.

So I think putting it all together, I think the rejection is completely erroneous. I don't really think that it fits.

I think no matter how you combine everything, you can take every piece from different types -- you can take a piece from the catheter, from the open-ended catheter, you can take a piece from the ablation catheter, you can put it all together which I don't even think is proper, but even if you do, you still don't have that helical coil with the engaging interlocking elements in a guide wire.

I hope that will be reversed and I appreciate this and thank you very much.

JUDGE SCHEINER: Thank you. Anything further?

Thank you for coming in.

MR. GERSTMAN: Well, thank you.

(Whereupon, the proceedings at 12:07 p.m. were concluded.)